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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/690,197	10/16/00	COLLINS D	COP1001

EXAMINER	
LUKTON,D	
ART UNIT	**PAPER NUMBER**
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DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/690,197	Collins
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 23, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-53 and 65-71* is/are pending in the applica

4a) Of the above, claim(s) *69-71* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-53 and 65-68* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Pursuant to the directives of paper No. 7 (filed 7/23/01), claims 54-64, 72-74 have been cancelled, and claims 1, 25, 31, 45-49, 65, 66, 68-70 amended. Claims 1-53, 65-71 are pending.

Applicants' election of Group 2 (claims 1-44, 49, 54-68, 72, limited to to compounds that contain B-10, with the further limitation that the "molecule comprising B-10" is a carbohydrate or nucleoside or carborane) is acknowledged. Claims 45-48 and 50-53 are joined therewith. Also acknowledged is applicants' attempt to comply with the "election of species" requirement. Applicants have elected compound 5 in figure 2; this is actually three separate compounds, "b"-monocarboxylic acid cyanocobalamin, "d"-monocarboxylic acid cyanocobalamin and the "b/d" dicarboxylic acid cyanocobalamin. Given that this is three compounds instead of one, applicants' election could be characterized as not fully responsive; however, the issue will not be pressed further at this time. The elected specie(s), however, does not contain a "detectable radionuclide". There are a number of claims, such as claim 44, which do not encompass the elected specie. Those claims not encompassing the elected specie are not withdrawn at this time; however, such claims may be withdrawn at a later time. Moreover, claims such as claim 65 do not require B-10; such claims are examined in part, and are still subject to restriction; such restriction may be enforced at a later time.

Applicants have requested that the method-of-use claims also be rejoined. The

corresponding method-of-use claims will be rejoined at a later time, subject to whatever limitations may be introduced into the Group 2 claims.

In this Office action, claims 1-53 and 65-68 are examined (in whole or in part). Claims 69-71 are withdrawn.

Applicants have also directed a change in the figure 1. A new formal drawing for this will be required. Applicants are reminded that as of November 7, 2000, no extensions of time for filing corrected or formal drawings in reply to a Notice of Allowability (PTO-37) are permitted.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 68 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 68 recites the term "pharmaceutical composition"; as such, an assertion of therapeutic or diagnostic utility is implied. However, neither is enabled. Based on the information provided (pp. 33-34), it appears that the following claim is enabled:

100. A method of inhibiting the binding of cyanocolablamin to a transcobalamin

protein comprising contacting a compound according to claim 1 with a transcobalamin protein for a time and under conditions effective to inhibit the binding of cyanocolablamin to the transcobalamin protein.

However, this is neither a therapeutic nor diagnostic utility. Perhaps also, there is enablement for a claim that is drawn to a method of *determining the anatomical location* of the compounds in question. Again, however, this is neither a therapeutic nor diagnostic utility. In addition, there is possibly a case to be made that, given what is known in the art about boron and neutron capture therapy, the following claim would be enabled:

101. A method of inhibiting growth of tumor cells comprising

(a) contacting tumor cells with a compound according to claim 1 for a time and under conditions effective to achieve binding between the tumor cells and the compound according to claim 1, and

(b) irradiating the tumor cells which have achieved binding with the compound according to claim 1, for a time and under conditions effective to inhibit growth of the tumor cells.

However, none of these methods is actually a therapy; in addition, while it should be possible to determine the location of the claimed compounds following administration to a mammal, there is no evidence that any of the claimed compounds will specifically localize at the site of a tumor.

Accordingly, it is suggested that applicants delete the term "pharmaceutical" from claim 68. (It is also suggested, but not yet required, that claims 69-71 be cancelled).

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Claims 1-49 and 65-68 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 is drawn to one "residue" that is linked to another "residue". As stated on page 14, the term "residue" is described as follows:

  > "A residue of a compound of formula I is a radical of a compound of formula I having one or more open valences. Any synthetically feasible atom or atoms of the compound... may be removed to provide the open valence, provided the resulting compound is able to localize in or near tumors..."

  However, this is not very meaningful. It would appear that the term "residue" could encompass a single carbon atom, or a single hydroxyl group. It this interpretation is not correct, applicants should explain why it is not. Better yet would be to mandate a specific core structure to be present. In addition to the foregoing, there is the matter of the letters a, b, c, d, e, f and g. If these are going to be present in the claim, their purpose must be explained.

- Claim 25 recites the presence of only one occurrence of a group of the formula Q-L-W-Det. However, claim 27 mandates the presence of two such groups. Accordingly, claim 27 is not properly subgeneric to claim 25; either claim 27 should be written in independent form, or else claim 25 should be re-worded to encompass the possibility of two groups the formula "Q-L-W-Det" being present.

- In claims 29 and 34, the abbreviations will have to be spelled out if they are going to be used.

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for the patent.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Primus (*Bioconjugate Chem* 7, 532, 1996).

Primus teaches (p. 534) boron-containing compounds.

This ground of rejection is intended to focus on the issues raised by the term "residue" in claim 1. As implied by the passage on page 14 of the specification, the term "residue" could be interpreted to refer to any fragment of cyanocobalamin, even a single carbon atom. Thus, for example, compound #6 (page 534, Primus) contains a hydroxyl group. This hydroxyl group can be viewed as a "residue" of the compound of formula I (instant claim 1). The remainder of compound #6 (page 534, Primus) can then be viewed as a "residue of a molecule comprising B-10". Similarly, compound #6 (page 534, Primus) contains a methyl group, which could be viewed as "residue" of the compound of formula I.

Thus, the claim is anticipated.

Those references stricken from the IDS were not received.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800